AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q86664

Application No.: 10/530,176

REMARKS

In the present Amendment, claims 1, 4 and 10 have been amended in response to the claim objection and the §112 rejection. Claim 23 has been amended to recite a <u>synergistic</u> pharmaceutical composition to more clearly characterize the present invention. No new matter has been added, and entry of the Amendment is respectfully requested.

Claims 1-4, 8-10 and 23 are pending.

Response to Claim Objections

Claims 1-4 and 8-10 are objected to because in claims 1 and 4, the specific groupings of cancers to agents allegedly are unclear due to the grammar/punctuation in the claims. The Examiner suggests the following format:

...wherein:

- (a) the cancer is ovarian, pancreatic or prostate cancer and the chemotherapeutic agent is cisplatin; or
 - (b) the cancer is ovarian and the chemotherapeutic agent is carboplatin; or
- (c) the cancer is ovarian or prostate cancer and the chemotherapeutic agent is paclitaxel; or
- (d) the cancer is ovarian or pancreatic cancer and the chemotherapeutic agent is gemcitabine or doxorubicin.

Claims 1 and 4 have been amended as suggested by the Examiner. Accordingly, withdrawal of the objection to the claims is respectfully requested.

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Response to § 112 Rejection

Claims 4 and 8-10 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the method of treating, allegedly does not reasonably provide enablement for the method of preventing. Even though the claims do not recite "preventing" cancer, the Examiner notes that the specification defines the term "treatment" to

The Examiner suggests amending claim 4 to state, A <u>method</u> combination therapy for the treatment of cancer comprising....

Claim 4 has been amended as suggested by the Examiner. Also, claim 4 has been amended to recite "doxorubicin" in the singular, for consistency.

include "preventing" a particular condition (page 17, lines 4-8).

Accordingly, withdrawal of the § 112 rejection is respectfully requested.

Response to § 103 Rejection

Claim 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kelly et al (W098/008503) in view of Ekwurlbe et al (US 6,380,405).

This rejection should be withdrawn because Kelly et al and Ekwurlbe et al do not disclose or render obvious the present invention, either alone or in combination.

Applicant previously argued that the claims have been amended to only recite the combinations that support the showing of unexpected results.

The Examiner disagrees, and points out that Claim 23 is not limited to specific cancers.

As such, the Examiner asserts that the skilled artisan would not have guidance as to what dosage amounts are required to make the composition limited to just the treatment of the specific cancers amended into claims 1 and 4.

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Applicant responds as follows.

Claim 23 has been amended to recite a "synergistic" combination of dehydroequol and the various chemotherapeutic agents. Applicant submits that one of ordinary skill in the art is able to determine the dosages that give synergistic results by consulting the specification and by routine experimentation.

In view of the above, present claim 23 is not obvious and is patentable over Kelly et al and Ekwurlbe et al, either alone or in combination. Reconsideration and withdrawal of the §103(a) rejection based on Kelly et al in view of Ekwurlbe et al are respectfully requested.

Response to Obviousness-Type Double Patenting

1. Claim 23 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,649,648 in view of Ekwurlbe et al (US 6,380,405).

This rejection should be withdrawn because present claim 23 is not obvious over the claims of the '648 Patent.

The Examiner maintains that the asserted unexpected superior results are not commensurate in scope with the scope of claim 23.

However, claim 23 as amended recites a "synergistic" combination of dehydroequol and the various chemotherapeutic agents. The claims of the '648 Patent do not teach dehydroequol in combination with cisplatin, carboplatin, paclitaxel, gemcitabine or doxorubicin.

Accordingly, present claim 23 is not obvious over the claims of the '648 Patent. Withdrawal of the double patenting rejection based on the '648 Patent is requested.

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2. Claim 23 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-38 of co-pending Application No. 10/547,077 in view of Ekwurlbe et al (US 6,380,405).

This rejection should be withdrawn because present claim 23 is not obvious over the claims of the co-pending '077 Application.

The Examiner maintains that the asserted unexpected superior results are not commensurate in scope with the scope of claim 23.

However, claim 23 as amended recites a "synergistic" combination of dehydroequol and the various chemotherapeutic agents. The claims of the co-pending '077 Application do not teach dehydroequol in combination with cisplatin, carboplatin, paclitaxel, gemcitabine or doxorubicin.

Accordingly, present claim 23 is not obvious over the claims of the co-pending '077 Application.

Additionally, the co-pending '077 Application claims priority to AU 2003906386 filed November 19, 2003, which is after Applicants' priority date of October 2, 2002. Accordingly, upon indication of allowable subject matter, the Examiner should remove this rejection. See MPEP 804(I)(B)(1).

In view of the above, withdrawal of the double patenting rejection based on the copending '077 Application is requested.

Allowable Subject Matter

The Examiner advises that Claims 1-4 and 8-10 are free of the prior art and will be allowed upon overcoming the rejection stated above.

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Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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